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and

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/020,337 | 12/12/2001 | Paul C. Peterson | CMI-425 | 1688 |
| 23720 | 7590 | 01/12/2004 | EXAMINER | |
| WILLIAMS, MORGAN & AMERSON, P.C. 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042 | | | CHATTOPADHYAY, URMI | |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 3738 |

DATE MAILED: 01/12/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|-----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/020,337 | PETERSON ET AL. |
| | Examiner | Art Unit |
| | Urmi Chattopadhyay | 3738 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 October 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-19 and 21-33 is/are pending in the application.
 - 4a) Of the above claim(s) 4-6, 9, 10 and 16 is/are withdrawn from consideration.
- 5) Claim(s) 17-19, 21-28 and 33 is/are allowed.
- 6) Claim(s) 1, 2, 7, 8, 11-15 and 29-32 is/are rejected.
- 7) Claim(s) 3 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 December 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 10/30/03 has been entered as Paper No. 6. Changes made to the specification to clarify the elected embodiment shown in Figures 12 and 13 have been approved by the examiner. Claim 20 has been canceled. The objections to the drawings are maintained because the replacement drawings that were to accompany the amendment (as indicated on page 13) were not attached. The examiner requests that these replacement drawings be provided in response to this office action. The rejection of claims 13-15 under 112, second paragraph is also maintained because contrary to page 14 of the amendment that states that claim 13 has been amended to overcome the rejection, the listing of the claims do not reflect an amended claim 13.

Election/Restrictions

2. Claims 1-19 and 21-33 are currently pending. The clarification of the elected embodiment of Figures 12 and 13 alters the status of the claims. Because the entire stent is coated with the polymeric material in a manner to leave an opening through the aperture, previously withdrawn claim 3 is no longer withdrawn from consideration. Claims 5, 6, 9, 10 and 16 remain withdrawn from consideration for being drawn to a non-elected species, and claim 4, which was previously examined, is also withdrawn.

3. Claims 17-19 and 21-33 are also no longer withdrawn from considered in view of the clarification. Claim 17 is generic and allowable. Accordingly, the restriction requirement as to the encompassed species is hereby withdrawn and claims 21, 22, 25, 26 and 33, directed to the

non-elected species are no longer withdrawn from consideration since all of the claims to this species depend from or otherwise include each of the limitations of an allowed generic claim.

4. In view of the above noted withdrawal of the restriction requirement as to the linked species, applicant(s) are advised that if any claim(s) depending from or including all the limitations of the allowable generic linking claim(s) be presented in a continuation or divisional application, such claims may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The claims being considered for further examination on the merits are 1-3, 7, 8, 11-15, 17-19 and 21-33. Claim 1 is generic.

Drawings

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: reference sign “XII-XII”, as mentioned on page 4, line 15, is not shown in Figure 12. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: reference sign “32” in Figure 2 and reference sign “66” in Figure 14 are not mentioned in the specification. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference

sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 32 requires the base to have a downstream edge wherein the apertures in the base are closer to the downstream edge than the upstream edge. There is no support for this in the specification. Applicant should clearly point out what is the downstream edge and how the apertures are closer to it than the upstream edge (74).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 and 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 13 and 29 recite the limitation "the suture apertures" in lines 2 and 3, respectively. There is insufficient antecedent basis for this limitation in the claim. Examiner suggests changing "the suture apertures" to --the apertures--.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 2, 7, 8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. (WO 00/23006 as cited in previous office action) in view of Reger (USPN 5,258,023 as cited in applicant's IDS).

Campbell et al. discloses a prosthetic heart valve having an inside and an outside with all the elements of claim 1, but is silent to the stent having a plurality of apertures providing openings between the outside and the inside of the prosthetic heart valve. See Figure 7 and page 3, lines 16-17 for polymeric valve body (12) having at least one leaflet (14) having an open and closed position and a stent (16) coupled to the valve body. See abstract and page 4, lines 15-18 for at least a portion of the stent (16) being embedded in the polymeric valve body. Reger teaches a prosthetic heart valve wherein a stent (30) has a plurality of apertures (142, 144, 146) penetrating a base portion of stent (claim 2) in order to reduce the likelihood of dehiscence by reducing the mass of the stent. See Figure 2 and column 8, lines 55-60. It would have been obvious to one of ordinary skill in the art that the time of applicant's invention to look to the teachings of Reger to modify the prosthetic heart valve of Campbell et al. by including apertures penetrating a base of the stent in order to reduce the mass of the stent to reduce the likelihood of dehiscence. Because the apertures are in the base portion of the stent that is not embedded in the polymeric valve body, they will provide openings between the outside and the inside of the

prosthetic heart valve. The apertures are also certainly *capable* of receiving sewing ring fasteners.

While Campbell et al. discloses a sewing ring (54) attached to the stent by sutures (56), Reger also teaches the additional limitations of claims 11 and 12, which require a sewing ring (102) to be attached to the stent (30) by sutures (188, 190) extending through the apertures in the stent. See Figure 7 and column 11, lines 28-32. It would have been obvious to one of ordinary skill in the art to look to the teachings of Reger to modify the prosthetic heart valve of Campbell et al. by attaching the sewing ring (54) of Campbell et al., which circumferentially surrounds the valve body and stent, to the stent by extending the sutures (56) through the apertures in the stent. Examiner contends that by extending the sutures (56) through the apertures rather than wrapping them around the stent the total length of suture used would be reduced, thereby reducing cost. In addition, the apertures could clearly indicate to the surgeon proper, equally spaced locations for suture placement to more evenly distribute the stress acting on the sutures.

Claim 7, see Figure 9 for sewing ring (54) circumferentially surrounding the base.

Claim 8, see Figure 10 for sewing ring being connected to the base at an upstream, inner side of the base via sutures (56).

13. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al. and Reger as applied to claim 1 above, and further in view of Lane (USPN 5,147,391 as cited in previous office action).

Campbell et al., as modified by Reger, discloses a prosthetic heart valve with all the elements of claim 1, but is silent to the additional limitation of the stent further comprising a wire

connected to the upstream edge wherein the apertures are downstream from the wire. See Figure 7 of Campbell et al. for the stent comprising an upstream edge. Lane teaches a prosthetic heart valve wherein a wire is connected to an upstream edge of the stent in order to restrict movement to the upper portion of the frame. See column 6, lines 19-26. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lane to modify the prosthetic heart valve of Campbell et al. and Reger by connecting a wire to an upstream edge of the stent in order to stiffen the lower portion of the stent and restrict movement to the upper portion of the stent. By connecting the wire to the upstream edge, the apertures will obviously be downstream from the wire.

Claims 14 and 15, see rejections of claims 11 and 12, supra.

Allowable Subject Matter

14. Claims 17-19, 21-28 and 33 are allowed.
15. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
16. Claims 29-32 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

17. Applicant's arguments filed 10/30/03 have been fully considered but they are not persuasive.
18. In response to applicant's argument that the teachings of Campbell et al. and Reger taken alone or together do not teach a prosthetic heart valve having a stent having apertures capable of receiving sewing ring fasteners to attach a sewing ring, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It is not required that Reger teach a separate sewing cuff that can be coupled to the heart valve using apertures in the stent or a stent that is at least partially embedded in a valve body. Reger is used to teach including apertures into the stent. Applicant should keep in mind that the limitation of "apertures being capable of receiving sewing ring fasteners" of claim 1 does not require that apertures are physically receiving sutures, but only that they are configured to be able to receive them.

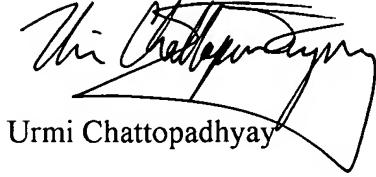
Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

Art Unit 3738

